DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 2 2001

Dr. Pauline Armstrong
Regulatory Affairs
Randox Laboratories Ltd.
Ardmore, Diamond Road
Crumlin, Co. Antrim
United Kingdom BT29 4QY

Re: 510(k) Number: K011302
Trade/Device Name: Randox Digoxin
Regulation Number: 862.3320
Regulatory Class: II
Product Code: KXT
Dated: April 20, 2001
Received: April 30, 2001

Dear Dr. Armstrong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): Not Known K011302

Device Name: DIGOXIN

Indications For Use :

The Randox Laboratories Ltd. Digoxin Test Kit is an *in vitro* diagnostic reagent for the quantitative determination of digoxin in serum. The method is a latex-enhanced immunoturbidimetric assay based on the principle of measuring changes in scattered light. Latex particles are coated with digoxin and, in the presence of digoxin antibody solution, rapid agglutination occurs. When a sample containing digoxin is introduced the agglutination reaction is partially inhibited, slowing down the agglutination process. The rate of agglutination is inversely dependent on the concentration of digoxin in the sample. By monitoring the change in scattered light as a change in absorbance, a concentration curve can be obtained. The actual change in absorbance is inversely proportional to the concentration of digoxin in the sample.

Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

These Application Sheets have been developed for the Hitachi 717 and Advia 1650 analysers and must be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011302

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109) (Optional format 1-2-96)